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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,307	11/19/2004	Hirofumi Doi	3190-066	6726

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KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,307	DOI ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 5, 7-9, 11, 12, 18-19, 31-35, 37-39, 42, 44-46, 48, 52, 55-56 drawn to an agent for inhibiting phosphorylation of c-Jun, a pharmaceutical composition comprising an agent, wherein the agent comprises one or more peptides selected from the following group: BMAL1, BPL1 or SEQ ID No:1-3.

Group II, claim(s) 3-4, 6, 13, 15, 16, 17, 40-41, 43, 50, 53 drawn to a method for inhibiting phosphorylation of c-Jun, a method for preventing or treating a disease and a method for inhibiting the ability of C-Jun to activate transcription, wherein the method comprises putting one or more peptides selected from the following group: BMAL1 and BPL1, or SEQ ID No: 1-3.

Group III, claim(s) 10, 20-26, 30, 36, 47, drawn to, a recombinant vector, a transformant transfected with a vector, a pharmaceutical composition comprising an effective dose of one or more polynucleotides encoding a peptide selected from the group: consisting of BMAL1, BPL1 or SEQ ID No: 1-3 and method of producing a polypeptide.

Group IV, claim(s) 14, 51 drawn to a method for preventing or treating a disease caused by the phosphorylation of c-Jun, wherein the method comprises utilizing one or more polynucleotides encoding encoding a peptide selected from the group: consisting of BMAL1, BPL1 or SEQ ID No:1-3.

Group V, claim(s) 27, drawn to a antibody that recognizes an agent for inhibiting phosphorylation of c-Jun, a pharmaceutical composition comprising an agent, wherein the agent comprises one ore more peptides selected from the following group: BMAL1 and BPL1, or SEQ ID No: 1-3.

Group VI, claim(s) 28, drawn to a method of identifying a compound that mediates or inhibits the interaction of an agent for inhibiting phosphorylation of c-Jun.

Group VII, claim(s) 29, drawn to a method of identifying a compound that mediates the expression of a poynucleotide that encodes a peptide selected from the group: consisting of BMAL1, BPL1 or SEQ ID No: 1-3.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-V appears to be that they relate to agents that inhibit the phosphorylation of c-June.

However Potapova et al., 2001 disclosoe agents that inhibit the phosphorylation of c-June; therefore the technical feature linking the inventions of Groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

Restriction Requirement Applicable to all Groups

Furthermore, in claims 1-56 the presence of multiple polypeptide sequences and polynucleotide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide and polynucleotide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody; also each one of the mentioned polynucleotides is capable of hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual evidence to the contrary. Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO: for prosecution on the merits.

Applicant is advised that a reply to this requirement must include an identification of SEQ ID NO: that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. The applicant should be aware that selection of a single SEQ ID NO: represents a response to a restriction requirement, **not an election of species**.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
Art Unit 1652


1-5-2007